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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,576	08/09/2001	Carsten Andersen	10004.204-US	2881

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NOVOZYMES NORTH AMERICA, INC.
500 FIFTH AVENUE
SUITE 1600
NEW YORK, NY 10110

EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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08/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/925,576	Applicant(s) ANDERSEN ET AL.	
	Examiner Manjunath N. Rao, Ph.D.	Art Unit 1652	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 July 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 23 July 2007. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): The rejection under 35 U.S.C. 112, 1st paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____
Claim(s) objected to: 26, 29, 50 and 57.
Claim(s) rejected: 25, 27-28, 30.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Manjunath N. Rao, Ph.D.
Primary Examiner
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Advisory Action

Claims 25-30, 50, 57 are now currently pending in this application.

Applicant's request for reconsideration filed on 3-19-04 has been considered and ENTERED. However, the claims are still not in condition for allowance for the following reasons.

In response to the previous Office action, applicant has amended some claims and traversed all the rejections. In response to the traversal of the rejection under 35 U.S.C. 112, 1st paragraph, without acquiescing to the applicant's arguments Examiner has withdrawn the rejection.

In response to the rejection of claims 25, 27-28 and 30 under 35 U.S.C. 102(b) Claims as being anticipated by Outtrup et al. (US 5,824,531, issued Oct.1998, and US 5856164, issued Jan 1999), applicant argues that the alpha-amylase of Outtrup et al. does not read on the claims as the claims are directed to "variant" alpha-amylases having a "substitution" at an amino acid position 118, 320 and/or 458 (using SEQ ID NO;12 for numbering). Applicant maintains, "as is well known in the art and described in the specification a "variant" is a polypeptide in which alterations have been introduced into the amino acid sequence by man" and refers to specification at page 3 (under the heading "Nomenclature"). Applicant argues that the claims are particularly directed to a "substitution" of a lysine at a position selected from the group consisting of 118, 320 and 458 and that as illustrated in the specification at page 3, a "substitution" is a change by man of one amino acid to another amino acid. Applicant maintains that thus, the claims specifically exclude the wild-type enzyme of Outtrup et al. as Outtrup et al. does not disclose a variant having a substitution of a lysine at a position selected from the group

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consisting of 118, 320 and 458 but rather, the lysine is naturally present at the corresponding position in the alpha-amylase of Outtrup et al. Examiner respectfully disagrees. Examiner has given the broadest interpretation as he is required to do so for the term "variant". Examiner also respectfully disagrees with the applicant's argument that it is well known in the art that a "variant" is a polypeptide in which alterations have been introduced into the amino acid sequence by man. While some variants are indeed created by man there is no established agreement or understanding that all or any "variant" is a polypeptide created by man. In fact variants are found in nature. Even more, given the broadest interpretation a "variant" polypeptide is a polypeptide which differs even by one amino acid from the reference sequence whether said difference is created by man or nature or by any other means or agent.

Furthermore, applicant's argument that the specification provides support for the definition of the variant in this application to be limited to sequence that is created by man is highly misplaced if not erroneous. This is because, a perusal of page 3 of the specification indicates no such specific definition that variants claimed in this application are limited to only those created by man. Also, even if it is agreed only for the sake of argument, that the variants claimed are man made, then these claims fall under the class of product by process claims. According to MPEP 2113, "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In this case, the claimed variant can be considered to be a product-by-process limitation. As such, the structure of the claimed variant

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protein has been interpreted to be the same as that of the structure of the reference polypeptide of Outtrup et al. Therefore contrary to applicant's argument, the claims are anticipated as written by Outtrup et al. Hence the rejection is maintained.

In response to the rejection of claims 25, 27-28 and 39 under 35 U.S.C, 102(e) as anticipated by US Patent Nos. 6,093,562, 6,187,576, 6,197,565; 6,204,232; 6,287,826; 6,297,038; 6,361,989; 6,486,113; 6,528 298; 6,673,589; 6,867,031 and 6,887 986; and due to Double Patenting rules, applicant argues that all these patents do not disclose a variant but a wild type enzyme and therefore do not anticipate. Examiner respectfully disagrees for the very same reasons he has argued for the rejection under 35 U.S.C. 102(b) above and continues to maintain the both above rejections.

Conclusion

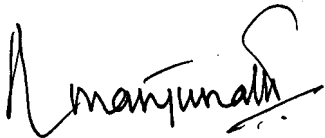
Claims 25, 27-28 and 30 are not allowed.

In view of the withdrawal of the rejection under 35 U.S.C. 112 1st paragraph, claims 26, 29, 50, 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including just the limitations of claim 26 (R118K).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is stylized with a large initial "M" and a long horizontal stroke.

Manjunath N. Rao, Ph.D.
Primary Examiner
Art Unit 1652

July 31, 2007